510(k) Summary of Safety and Effectiveness

APR 19 2011

Submitter Information

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Name of contact person:	James McMahon Manager, Regulatory Affairs Covidien 15 Crosby drive Bedford, MA 01730 USA Phone: (781) 839 1787
Date prepared:	April 15, 2011

Name of device

Trade or proprietary name:	PARIETEX™ Optimized Composite Mesh
Common or usual name:	Surgical Mesh
Classification name:	Mesh, Surgical, Polymeric
Classification panel:	General and Plastic Surgery (79)
Regulation:	21 CFR 878.3300
Product Code:	FTL

Legally marketed devices to which equivalence is claimed: PARIETEX™ Composite Mesh (K002699, K040998 and K050187)

Reason for 510(k) submission: The proposed PARIETEX™ Optimized Composite Mesh (PCO-OSX references) has been modified compared to the predicate devices as the knitting three dimensional textile has been modified to obtain a higher mechanical resistance of the mesh and the collagen film formulation has been changed to get a film more resistant to handling.

Device description:

The PARIETEX™ Optimized Composite Mesh is available in rectangular and round shape. This device is made out of a three dimensional multifilament polyester knit for wall reinforcement, covered with an absorbable, continuous and hydrophilic film on one of its sides. This film is made up of collagen from porcine origin and glycerol, and juts out 5 mm over the edge of the reinforcement. A bi-dimensional multifilament polyester textile flap is attached to the three-dimensional reinforcement.

Intended use of the device:

The PARIETEX™ Optimized Composite Mesh is used for the reinforcement of tissues during surgical repair.

Indications for use:

It is indicated for the treatment of incisional hernias, abdominal wall repair and parietal (i.e. pertaining to the walls) reinforcement of tissues. The non-absorbable three-dimensional polyester mesh provides long term reinforcement of soft tissues. On the opposite side, the absorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera.

Summary comparing the technological characteristics of the subject and predicate devices:

The proposed PARIETEX™ Optimized Composite Mesh is equivalent to the predicate devices PARIETEX™ Composite Mesh (K002699, K040998 and K050187) in terms of its technological characteristics. No major technological changes are proposed to the predicate devices in this submission. Design modifications include a new collagen film formulation and changes to the knitting pattern. Performance testing was performed on both predicate and proposed mesh. The results of a pre-clinical study and bench testing, performed in accordance with FDA's Guidance for the Preparation of a Premarket Notification Application for Surgical Mesh, demonstrate improved mechanical properties, and equivalent *in-vivo* minimizing tissue attachment property.

Performance data:

Bench testing and pre-clinical testing has been conducted to evaluate the performance characteristics. Testing has shown that the PARIETEX™ Optimized Composite Mesh is equivalent in performance characteristics to the predicates PARIETEX™ Composite Mesh.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR 19 2011

Sofradim Production
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Mr. James McMahon
15 Crosby Drive
Bedford, Massachusetts 01730

Re: K110816
Trade/Device Name: PARIETEX™ Optimized Composite Mesh (PCO-OSX references
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: March 22, 2011
Received: March 25, 2011

Dear Mr. McMahon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known):

Device Name: PARIETEX™ Optimized Composite Mesh
(PCO-OSX references)

Indications For Use:

The PARIETEX™ Optimized Composite mesh is used for the reinforcement of tissues during surgical repair. It is indicated for the treatment of incisional hernias, abdominal wall repair and parietal (i.e. pertaining to the walls) reinforcement of tissues. The non-absorbable three-dimensional polyester mesh provides long term reinforcement of soft tissues. On the opposite side, the absorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110816